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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/632,054

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Robert E. Richard

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EXAMINER

HUGHES, ALICIA R

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

10/30/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/632,054	RICHARD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ALICIA R. HUGHES	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-29 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 19-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 16-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims and Examination***

Claims 1-13 and 15-29 are pending. Claims 1-13 and 16-18 are the subject of this Office Action. Claims 15 and 19-29 have been withdrawn from consideration, being drawn to a non-elected invention. Applicants cancelled claim 14 in their filing of 17 October 2008.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicants' arguments filed on 17 October 2008 have been fully considered but are deemed to be persuasive regarding the previous rejection. Rejections not reiterated from this Office's previous action are hereby withdrawn. The rejections set forth herein constitute the complete set of rejections being applied to the instant application presently.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

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application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 and 16-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent Application No. 10/894,400. The rejection as written in this Office's Action of 14 June 2007 is extended and fully incorporated herein by reference.

Claims 1-13 and 16-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-23 of U.S. Patent Application No.

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10/632,008. The rejection as written in this Office's Action of 14 June 2007 is extended and fully incorporated herein by reference.

Claims 1-13 and 16-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent Application No. 10/409,358. The rejection as written in this Office's Action of 14 June 2007 is extended and fully incorporated herein by reference.

In response the above rejections, Applicants, in their remarks of 14 December 2007 and of 17 October 2008 declined to discuss the merits but rather, have opted to address these provisional rejections at a future time when these rejections only remain. Until such time, the rejections are considered proper and maintained.

### ***Claim Rejections – 35 U.S.C. §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4-9 are rejected under 35 U.S.C. §102(b) as being anticipated clearly by U.S. Patent No. 5,674,242 [hereinafter referred to as "Phan et al"]. The rejection as set forth in this Office's Actions on 14 June 2007 and 17 December 2008 are incorporated herein by reference in their entirety.

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In response, Applicants have amended claim 1 to incorporate a limitation that the polymeric release region further comprise a “polymer selected from the group consisting of homopolymers and copolymers containing polytetrafluoroethylene, collagen, cellulose, polyisobutylene, poly(2-methyl butane), and poly(2-methyl pentene)” and now argue that: (1) Phan et al do not teach the claimed polymers in light of the new limitation; (2) there is no teaching or suggestion in Phan et al of polymers in which radiation is used to increase release of a therapeutic agent from a polymer; and (3) inherency cannot flow as a necessary conclusion of the teachings of Phan but rather, Phan et al teaches away from the inherency required to support a rejection of the stated claims as anticipated.

Contrary to Applicants’ assertion, Phan et al do teach polymer members that include cellulose and collagen (Col. 6, line 60 and Col. 10, lines 29-32), as included in Applicants’ amended claim 1.

Also, Applicants’ argument that there is no teaching or suggestion in Phan et al of polymers in which radiation is used to increase release of a therapeutic agent from a polymer is unfounded. Rather, as noted in the Office Action of 17 April 2008, it necessarily flows that the same therapeutic agent comprising the same polymeric release region is used in the same host, subject to a radiation dose that gives the same effect to the same patient population (Please see Col. 6, lines 29-33). And further as note prior, by Applicants’ own account,

“when polymers are exposed to radiation, at least two *reactions are believed* to occur” and “[c]rosslinking *generally* results in ...[and c]hain scission, on the other hand *generally results* in ...While polymers *may display* both types of reactions, one type of reaction will *typically* dominate. For increased release, *it is preferred to use polymers* in which chain scission reactions dominate.” (Emphasis added).

In light of the foregoing, Claims 1 and 4-9 are clearly anticipated by Phan et al.

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***Claim Rejections – 35 U.S.C. §103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-14 and 16-18 are rejected under 35 U.S.C. 103(a) as being obvious over Phan et al in view of U.S. Patent Publication 2002/0107330 A1 [hereinafter referred to as “Pinchuk et al”](please refer to Pinchuk et al in its entirety) and in further view of U.S. Patent Publication No. 2002/0099438 A1 [hereinafter referred to as “Furst”].

The teachings of Phan et al and related arguments, *supra*, and as well, the teachings of Phan et al and Pinchuk et al from this Office’s Actions of 14 June 2007 and 17 April 2008 are incorporated herein by reference in their entirety. Applicants’ primary argument is that this rejection fails for the reasons set forth in response to this Office’s 102(b) reference, as stated *supra*, noting the alleged irrelevance of Phan et al to the instant claims. For the reasons set forth above, Phan et al is deemed relevant and extended to this rejection.

Further, Applicants now argue that there is nothing in the prior art that would cause one of ordinary skill in the art to appreciate that methacrylate-containing or acrylate-containing polymers and polystyrene-polyisobutylene-polystyrene copolymers are functional equivalents of one another thereby making substitutions thereof in the art *prima facie* obvious. The Office’s position in regard to this particular point as set forth in the previous rejection, notably relying on the Furst reference, is hereby maintained for reasons already made of record.

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In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to develop a stent comprising a triblock copolymer such as polystyrene-polyisobutylene-polystyrene which comprises a plurality of  $-\text{CH}_2-\text{CR}_1\text{R}_2$  groups and houses a therapeutic agent for release.

Claims 2-3 are rejected under 35 U.S.C. 103(a) as being obvious over Phan et al in view of U.S. Patent Publication No. 6,537,569 [hereinafter referred to as "Cruise"] (please refer to Cruise in its entirety).

The teachings of Phan et al and related arguments, *supra*, and as well, the teachings of Phan et al and Cruise et al from this Office's Actions of 14 June 2007 and 17 April 2008 are incorporated herein by reference in their entirety. Applicants' lone argument is that this rejection fails for the reasons set forth in response to this Office's 102(b) reference, as stated *supra*, noting the alleged irrelevance of Phan et al to the instant claims. For the reasons set forth above, Phan et al is deemed relevant and extended to this rejection.

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to develop a stent with a polymeric release region and therapeutic agent wherein the polymeric release region would be treated with a radiation dose in excess of 10,000,000 rads to increase the cumulative release of the therapeutic agents therein.

### **Conclusion**

No claims are allowed.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/

Examiner, Art Unit 1614

/Raymond J Henley III/  
Primary Examiner, Art Unit 1614